

Implementation of the Biomaterials Access Assurance Act of 1998;

Draft Guidance for Industry and FDA

Draft Guidance – Not for Implementation

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Office of the Director
Office of Compliance**

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Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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Guidance for the Implementation of the Biomaterials Access Assurance Act of 1998.

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Background

A. General

The Biomaterials Access Assurance Act of 1998 (BAA98) (21 U.S.C. 1601-1606) establishes a mechanism to protect some biomaterial suppliers of implanted medical devices from liability in civil suits. For the purposes of this act, a "biomaterials supplier" is defined as an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implanted medical device. In accordance with BAA98, except as provided, "a biomaterials supplier shall not be liable for harm to a claimant caused by an implant." Under the statute, a biomaterials supplier may be liable for damages:

1. when the supplier acts as the manufacturer of the implanted device;
2. when the supplier acts as the seller of the implanted device;
3. when the supplier fails to meet specifications; or
4. when the supplier has substantial economic ties to either the manufacturer or the seller of the implanted device.

BAA98 also provides that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of a Food and Drug Administration (FDA) declaration that states that the supplier was required to register under 21 U.S.C. 360, but failed to do so, or was required to list its device under 21 U.S.C. 360(j), but failed to do so.

The act allows persons to petition the FDA for a declaration that a biomaterials supplier should have registered or listed with the FDA and failed to do so.

II. Petition for Declaration

A. Prerequisites for Filing a Petition for Declaration

The petition should provide information that shows that the prerequisites specified in BAA98 for filing a petition are met. The prerequisites include the following:

1. A civil suit has been filed in a State or Federal court for harm allegedly caused, directly or indirectly, by an implant.
 - Exception: A civil suit for harm suffered from loss of or damage to an implant, or commercial loss to the purchaser from loss or damage of the implant is not affected by BAA98.
2. The suit was filed after August 13, 1998.
3. The manufacturer of the implant must be named as a party to the civil action.
 - a. Exception: The manufacturer of the implant is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to service.
 - b. Exception: A claim against the manufacturer is barred by an applicable law or rule of practice.

B. Contents of the Petition

The petition should provide information that shows that a biomaterials supplier should have registered or listed with FDA but failed to do so. To ensure that sufficient information is included in the petition, petitions should:

1. Identify the final product and how it is intended to be used.
2. Identify specifically what activities the supplier performs with respect to the device.
3. Identify the name and type of entity/person to which the supplier sends the device.

C. Summary of Establishment Registration and Device Listing Activities

The rules regarding who must register and list with the FDA are detailed in 21 CFR 807, Subparts A, B, and C.

D. Statute and Regulations relevant to preparation of Petition for Declaration

Petitioners should consult the following statutes and regulations when preparing a petition.

1. The registration provisions in section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360)
2. The regulations issued under section 510 of the Act

3. The listing provisions in section 510(j) of the Act
4. The regulations issued under section 510(j) of the Act
5. The regulations in part 807 (21 CFR 807).

E. Submission of Petition

Petitions should be submitted to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

III. Notice of Opportunity for Hearing

In accordance with Sec. 5(b)(3)(A) of BAA98, both notice to the affected persons and an opportunity for an informal hearing must be provided before a declaration may be issued by the Secretary. When a notice of opportunity for hearing is issued, its contents should include the following:

1. Whether the petition meets prerequisites for filing
2. Whether and why FDA proposes to grant or deny the petition for declaration
3. Language giving an opportunity for affected persons to request a hearing and asking such affected persons to provide data and information in support of their hearing request

IV. Final Decision

When FDA issues a final decision on a petition, it will include the following determinations:

1. Whether the petition meets prerequisites for filing.
2. Whether and why FDA grants or denies the petition for declaration.

V. Administrative Procedures

A. Sequence of Events

The following lists the sequence of events that will take the Petition for Declaration from its initial receipt by the Agency through to the final decision on the petition. The Office of Compliance should consult with the Office of Chief Counsel as needed.

1. Dockets receives the Petition for Declaration and files it
2. Dockets forwards the Petition to the Regulations Staff (HFZ-215)
3. Regulations Staff forwards the Petition to Office of Compliance to write the response
4. Office of Compliance reviews the petition
5. Office of Compliance writes a notice of opportunity for hearing (preliminary determination and opportunity for hearing)

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6. Office of Compliance mails (registered) the notice of opportunity for hearing (NOOH) to the affected persons

7. Affected persons have 10 days to request a hearing

next steps are either 8 + 9 OR 8A + 9A:

8. Affected persons do not request a hearing

9. Office of Compliance issues a final decision **next step is 14**

- 8A. Affected persons request a hearing and submit data and information in support of the request

- 9A. Office of Compliance reviews hearing request

next step is either 10 OR 10A:

10. Office of Compliance issues a final decision denying the hearing request and either grants or denies the petition **next step is 13**

- 10A. Office of Compliance decides a Part 16 hearing should be granted

11. Hearing is held

next step is either 12 OR 12A:

12. Hearing officer issues the final decision that denies the petition **next step is 14**

- 12A. Hearing officer issues the final decision that grants the petition

13. Office of Compliance issues the declaration as instructed by the hearing officer

14. Office of Compliance or the hearing officer submits the written final decision to Dockets for filing

B. Timeline for Administrative Procedures

Given the 120-day final decision time limitation stipulated by 21 U.S.C. 1604(b)(3)(B), the Office of Compliance may find it helpful to develop a timeline for key milestones in this process for each petition received. An example of a timeline is as follows:

1. Day 1 – Petition Filed in Dockets
2. Day 30 – NOOH Drafted
3. Day 40 – Hearing request due with supporting data and other information
4. Day 75 – If hearing request is granted, schedule hearing request
5. Day 90 – Hearing
6. Day 105 – Hearing officer order due and mailed
7. Day 120 – Final decision drafted and mailed

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3. Regulations Staff forwards the Petition to Office of Compliance to write the response
 4. Office of Compliance reviews the petition
 5. Office of Compliance writes a notice of opportunity for hearing (preliminary determination and opportunity for hearing)
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